

**Notice of Allowability**

Application No.

10/723,807

Applicant(s)

BLINKOVSKY ET AL.

Examiner

Nashaat T. Nashed, Ph. D.

Art Unit

1656

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to filing the application on 11/25/03.
2. ☒ The allowed claim(s) is/are 1-15 and 18.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date 11/25/03 | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                        | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9. <input type="checkbox"/> Other _____.   |

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Claims 1-20 are pending and under consideration.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15 and 18, drawn to a method of making protein hydrolysate, classified in class 435, subclass 68.1.
- II. Claims 16, 17, 19, and 20, drawn to a protein hydrolysate, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of invention II can be made by a different process such as synthesizing different peptides and amino acids and mixing them together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Robert Starnes on January 5, 2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-15 and 18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 16, 17, 19 and 20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Robert Starnes on January 25, 2006 and January 26, 2006.

The application has been amended as follows:

- (I) Delete non-elected claims 16, 17, 19, and 20.
- (II) Amend claims 1, 2, 10, 14 and 18, as shown bellow:

- Claims 1 A method for producing a hydrolysate from a proteinaceous substrate which comprises subjecting the substrate to a polypeptide having dipeptidyl aminopeptidase activity and an endopeptidase, wherein the polypeptide having dipeptidyl aminopeptidase activity is selected from the group consisting of:
- (a) a polypeptide having an amino acid sequence which has at least 95% identity with amino acids 17 to 771 of SEQ ID NO:2;
  - (b) a polypeptide which is encoded by a nucleic acid sequence which hybridizes under high stringency conditions with (i) nucleotides 49 to 2396 of SEQ ID NO. 1, or (ii) the cDNA sequence corresponding to nucleotides 49 to 2396 of SEQ ID NO. 1, wherein high stringency conditions are defined as prehybridization and hybridization at 42 °C in 5X SSPE, 0.3% SDS, 200 µg/ml sheared and denatured salmon sperm DNA, and 50% formamide, and washing with 2X SSC, 0.2% SDS at 65 °C; and
  - (c) a fragment of (a) or (b), wherein the fragment has dipeptidyl aminopeptidase activity.
- Claim 2 The method of claim 1, wherein the polypeptide having dipeptidyl aminopeptidase activity ~~aminopeptidase activity~~ comprises an amino acid sequence which has at least 95% identity with amino acids 17 to 771 of SEQ ID NO:2.
- Claim 10 The method of claim 1, wherein the polypeptide having dipeptidyl aminopeptidase activity ~~aminopeptidase activity~~ is encoded by a nucleic acid sequence which hybridizes under high stringency conditions with (i) nucleotides 49 to 2396 of SEQ ID NO. 1, or (ii) the cDNA sequence corresponding to nucleotides 49 to 2396 of SEQ ID NO. 1, wherein high stringency conditions are defined as prehybridization and hybridization at 42 °C in 5X SSPE, 0.3% SDS, 200 µg/ml sheared and denatured salmon sperm DNA, and 50% formamide, and washing with 2X SSC, 0.2% SDS at 65 °C.
- Claim 14 The method of claim 1, further comprising the addition of another ~~wherein the polypeptide having dipeptidyl aminopeptidase activity acts synergistically with an~~ aminopeptidase to hydrolyze a polypeptide.

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Claim 18 A method for producing a hydrolysate from a proteinaceous substrate which comprises subjecting the substrate to a polypeptide having dipeptidyl aminopeptidase activity from *Aspergillus* strain ~~and an endopeptidase~~, wherein the polypeptide having dipeptidyl aminopeptidase activity has the following physicochemical propedies: (a) a pH optimum at about pH 8.7 determined after incubation for 5 minutes at ambient temperature in the presence of 2.9 mM Ala-pro-para-nitroanilide, (b) a temperature stability of 90% or more, relative to initial activity, after incubation for 20 minutes at 65 °C, pH 7.5 in the absence of substrate, wherein remaining activity was determined with 2.9 mM Ala-pro-para-nitroanilide in 50 mM sodium phosphate PH 7.5, (c) activity towards Xaa-pro-para-nitroanilide or Xaa-Ala-para-nitroanilide at ambient temperature in 50 mM sodium phosphate pH 7.5, wherein Xaa is selected from the group consisting of Ala, Arg, Asp, Gly, and Val; and (d) a molecular weight of about 93-96 kDa by SDS-PAGE.

Claims 1-15 and 18 are allowed.

The following is an examiner's statement of reasons for allowance: The claims of the instant application are directed to a method of making a protein hydrolysate using a dipeptidyl aminopeptidase having the amino acid sequence of SEQ ID NO: 2 and encoded by the nucleic acid sequence of SEQ ID NO: 1 from *Aspergillus oryzae*. Claims directed to said aminopeptidase with the same scope as those of the instant claims and nucleic acid encoding said amino peptidase were allowed in the parent application serial number 09/079,592, filed May 15, 1998, now U. S. patent 6,664,092. Both aminopeptidase and the nucleic acid encoding the same remain free of prior art, and therefore, the claims are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTWTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen M. Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.  
Primary Examiner  
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